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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,039	07/31/2003	Szu-Min Lin	JJM-346CIP1	9647

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EXAMINER	
JOYNER, KEVIN	
ART UNIT	**PAPER NUMBER**
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,039	LIN ET AL.	
	Examiner	Art Unit	
	Kevin C. Joyner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fry et al. (U.S. Patent No. 3893843) in view of Addy et. al. (U.S. Patent No. 5961921).

Fry discloses a method for cleaning and sterilizing a medical device (as disclosed in column 1 line 5), comprising the steps of: placing the device into a container (referenced as a tub in column 3 line 8); cleaning the device in the container with a cleaning solution (referenced as a washing liquid in column 3 line15); and rinsing the device in the container with a rinse solution (as disclosed in column 3 line 31). Fry does not appear to disclose vaporizing a liquid substance in the container to create a sterilant vapor and contacting the device with the vapor to effect sterilization of the device. Addy discloses methods for peroxide vapor sterilization of medical devices. The patent further discloses a method comprising the step of vaporizing a liquid substance in the container to create a sterilant vapor and contacting the device with the vapor to effect sterilization of the device (as disclosed in column 2 lines 54-58). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

method as shown by Fry to include the step of vaporizing a liquid substance in the container to create a sterilant vapor and contacting the device with the vapor to effect sterilization of the device in view of Addy in order to produce a sterile tool without the need of a final rinsing step.

Concerning the limitations of claims 6-8, Fry is relied upon as set forth in regards to claim 1. Fry does not appear to disclose a method wherein the liquid substance comprises a chemical sterilant and wherein the chemical sterilant comprises hydrogen peroxide, or a method further comprising introducing the liquid substance as a mist. Addy is relied as set forth in regards to claim 1, and further discloses a method wherein the liquid substance comprises a chemical sterilant and wherein the chemical sterilant comprises hydrogen peroxide (as disclosed in column 2, lines 59-61) as well as a method further comprising introducing the liquid substance as a mist (column 3, line 10 states that the introduction of the liquid substance can happen in a plurality of ways including aerosol spray. As broadly interpreted, an aerosol spray produces a mist.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for Fry to include the liquid substance comprising a chemical sterilant and wherein the chemical sterilant comprises hydrogen peroxide, which is a commonly known sterilizing chemical as exemplified by Addy.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fry in view of Addy as applied to claim 1 above, and further in view of Langford (U.S. Patent No. 5,711,921).

Fry in view of Addy is relied upon as set forth in reference to claim 1. Fry in view of Addy does not appear to disclose a method according to claim 1 further comprising storing the device in the container in sterile form. Langford discloses a method with an improved apparatus, which can be used, for cleaning and/or sterilizing devices. The patent further discloses a method comprising storing the device in a container in sterile from (as disclosed in column 6, lines 32-37; the device is an endoscope). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method as shown by Fry in view of Addy to include the step of storing the device in the container in sterile form as shown by Langford. This eliminates the need for transporting the sterilized device to a storing compartment thus reducing the chances for the device to become contaminated again.

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fry in view of Addy as applied to claim 1 above, and further in view of Langford (U.S. Patent No. 5,443,801).

Fry in view of Addy is relied upon as set forth in reference to claim 1. Fry in view of Addy does not appear to disclose a method according to claim 1 wherein the liquid substance comprises a retained portion of the rinse solution. Mariotti discloses a method that includes a device for cleaning, disinfecting and/or drying an endoscope. The patent further states during one of the method steps that a liquid substance comprises a retained portion of a rinse solution (Column 8, paragraph 1 states that a disinfecting sequence takes place in two steps. The first is injected into a line, which is continually recycled through a recycling pump (more information on the recycling stream

is disclosed in column 5, lines 28-39). As broadly interpreted, this is a rinsing step. The second step consists of adding a second dose of disinfectant to the stream of the first step, which makes up a liquid substance. As broadly interpreted, this discloses a liquid substance comprising a retained portion of a rinse solution.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method as shown by Fry and Addy to include a method step that a liquid substance comprises a retained portion of a rinse solution as shown by Mariotti. This would minimize the amount of material used during the sterilization process.

4. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fry in view of Addy as applied to claim 1 above, and further in view of McConnell et al. (U.S. Patent No. 4,917,123).

Fry in view of Addy is relied upon as set forth in reference to claim 1. Fry in view of Addy does not appear to disclose a method according to claim 1 wherein the rinse solution comprises a chemical sterilant and wherein the chemical sterilant comprises hydrogen peroxide. McConnell discloses a method for the sterilization of wafers in which a rinse solution is used. The patent further discloses that a rinse solution comprises a chemical sterilant and wherein the chemical sterilant comprises hydrogen peroxide (as disclosed in column 16, lines 52-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Fry and Addy to include a rinse solution comprising a chemical sterilant and wherein the chemical sterilant comprises hydrogen peroxide. As exemplified by McConnell it is a commonly known chemical sterilant for rinsing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 4-8 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 21, and 24 of U.S. Patent No. 6589481. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims fully encompass the claims of the instant application. The patent claims a method for pretreating a lumen device with hydrogen peroxide. The method includes contacting the device with a hydrogen peroxide solution, placing the device in a container. Removing the solution from the chamber and introducing a sterilant to the lumen. The sterilant is hydrogen peroxide

and is vaporized onto the lumen. In claim 24, line 2, the patent claims that the sterilant is introduced as a mist.

Terminal Disclaimer

6. The terminal disclaimer filed on January 16, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,203,756 and 6,187,266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

7. Applicant's arguments filed January 16, 2007 have been fully considered but they are not persuasive.

Applicant's principle arguments are:

(a) There is no suggestion for making the alleged combination of Fry in view of Addy for claims 1 and 6 to 8. The examiner has merely stated the teachings of the references ands asserted without further justification that the combination would be obvious. Accordingly, Applicants respectfully submit that the Examiner has failed to establish a prima facia case obviousness.

As discussed above and explained in further detail herein, the method of Fry washes and disinfects medical devices comprising the steps of:

Placing the articles in a container, washing the articles in the container, rinsing the articles, disinfecting the articles, and rinsing the articles again after disinfecting the

articles in order to thoroughly remove the disinfecting solution from the articles as disclosed in column 2, lines 4-13: column 3 lines 43-57. Addy discloses a method of sterilizing medical devices as well wherein the method includes placing a device in a container, and vaporizing a liquid substance in the container to a sterilant vapor and contacting the device with the vapor to effect sterilization of the device as disclosed in column 2, lines 50-65. Addy further discloses that the step of vaporizing a sterilant solution reduces the exposure time and lowers the concentration of the disinfecting solution needed to effectively sterilize the articles (column 1, lines 30-32; column 8, lines 53-55; column 10, lines 33-42; column 27, lines 57-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Fry by vaporizing the sterilant solution as an alternative to rinsing the disinfectant solution in order to reduce costs, reduce the level of toxic residues, and increase efficiency as shown by Addy.

(b) If the references of Fry in view of Addy were combined, the alleged combination would fail to reach the claimed invention. If the teaching of these two reference were to be combined it would result in a two step process in which first an object might be washed in the device of Fry and then afterward removed from the device of Fry and process in the device of Addy. It would not lead to the step of vaporizing a liquid substance in the same container in which the cleaning and rinsing had occurred.

As discussed above Addy teaches that in the method of sterilizing articles, vaporization of the disinfectant liquid provides advantages over liquid sterilization in that

it reduces the exposure time needed to sterilize the substance and reduces the concentration needed in the sterilizing substance when compared to traditional sterilization by using liquid disinfecting solutions without vaporization.

(c) The examiner rejected claims 1 and 4 to 8 on the ground of obviousness type double patenting over claim 16, 21 and 24 of U.S. Patent No. 6,589,481. There is nothing in these claims which speak to the steps of cleaning and rinsing the device in the same container in which the vaporization of sterilant occurs.

As disclosed in claim 16 of U.S. Patent No. 6,589,481 the reference applies a liquid to an article comprising hydrogen peroxide and removes the liquid from the article. This is the step of cleaning the device that occurs inside a chamber. A liquid sterilant is then introduced into the chamber to the article. As broadly defined this is rinsing the article. The liquid sterilant, which is a liquid substance, is then vaporized in the container and contacts the device for sterilization. Thus all of the limitations of the claims 1 are encompassed and/or are obvious over claim 16 of U.S. Patent No. 6,589,481.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Joyner whose telephone number is (571) 272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER

KCJ